

rec'd
9/16/04

September 7, 2004

Mr. Robert Moore
Office of Nutritional Products
HFS-811
FDA
5100 Paint Branch Parkway
College Park
MD 20740

Dear Mr. Moore,

We have been made aware of a regulation that requires our company to submit our labeling to you shortly after the initiation of commercial marketing. Please accept this submission for our product labeling as described in 21 CFR 101.93.

21 CFR 101.93 (2) (i)

Name and Address of Manufacturer:

Arizona Nutritional Supplements
380 East Chilton Drive
Chandler,
Arizona 85225

21 CFR 101.93 (2) (ii)

Text of the Statements:

The Hearing Pill contains pharmaceutical grade active ingredient and is measured to strictly conform with United States Pharmacopoeia. This product is protected under the US Navy and State University of New York #6,177,434 patent.

Mechanism: The Hearing Pill has demonstrated to help increase the levels of protective compounds and reduce the levels of destructive compounds in the cochlea.

Indications: The Hearing Pill is indicated for the remediation of the mechanisms that lead to permanent hearing loss, either before or shortly after noise trauma, after diagnosis by a qualified physician. Take only as part of an effective hearing conservation program.

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Directions: Take two capsules twice daily before entering into a noisy environment such as a shooting range, rock concert or construction site. After experiencing nose trauma, see your physician immediately, and take two capsules three times daily for 30-60 days to attain the most positive effects.

Warnings: Seek the advice of a qualified health professional before using this product. The most common side effects are upset stomach and diarrhea. If symptoms continue to persist after a reasonable period of time, or if symptoms get worse, consult your doctor. Keep out of the reach of children.

The following "Supplement Facts" are on the left side of the product label:

Supplement Facts	
Serving Size Two Capsules	
Amount Per Serving	
N-Acetyl Cysteine	800mg*
* Daily Value Not Established	

Other Ingredients: Rice Flour, Magnesium Stearate

Active Ingredients: 100% Pharmaceutical grade N-Acetyl Cysteine (NAC).

Store in a cool dry place. Do not use if seal is broken.

American BioHealth Group
San Diego, CA 92128

For reorders and more information visit
www.thehearingpill.com

For Comments and/or Questions Call
(858) 675-3600

* This product has not been approved by the FDA, and is not intended to diagnose, treat, cure or prevent any disease.

I hereby certify that the information contained in this notice is complete and accurate, and that American BioHealth Group has substantiation that the statements are truthful and not misleading.

Best Regards,

A handwritten signature in black ink, appearing to read "Mark Mugerditchian", followed by a horizontal line.

Mark Mugerditchian
President and COO
American BioHealth Group

Attachments: Full Product Label

BONUS AMOUNT INCLUDED * BONUS AMOUNT INCLUDED * BONUS AMOUNT INCLUDED * BONUS AMOUNT INCLUDED * BONUS AMOUNT INCLUDED

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THE HEARING PILL™

*helps promote better hearing**

Safety Tested and
Quality Assured

AIDS IN
PROTECTING
YOUR HEARING*

Guaranteed or
your Money Back

PROTECTED UNDER U.S. PATENT 6,177,434

**American
BioHealth**
Group

90 EASY-TO-SWALLOW CAPSULES

MADE IN THE USA

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